INTEROFFICE MEMORANDUM

Date: 10-Feb-1999 09:50am
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To: cerny@cder.fda.gov (cerny@A1)

Subject: 4 Aminopyridine

Hi Igor, attached is my attempt at providing information and testimony for the committee. I approached it on a more human experience position rather than just citing clinical research statistics that the committee probably already has. If this approach is not appropriate or if you think clinical research stats need to be submitted, please advise. In any event, let me know what you think about my brief submission.
Thanks, Art Hulkoff

98N-0182

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TO: FDA PHARMACY COMPOUNDING ADVISORY COMMITTEE

RE: REQUEST TO INCLUDE 4 AMINOPYRIDINE ON THE BULK DRUGS LIST

I am requesting that the compounded drug 4 Aminopyridine be included on the Bulk Drugs List.

On behalf of my wife, who has multiple sclerosis and myself, we feel that 4AP should continue to be available through the prescription by a physician and compounded by a licensed pharmacist. My wife has taken low doses of 4AP for approximately 6 months with modest but positive results. As clinical research on 4AP has demonstrated in the past , 4AP enhances the neurological conduction through those neurons damaged by the demyelination occurring with MS.

The unique effect of the 4AP in restoring the cellular chemical balance lost from demyelination is important in the potential for improvement in nerve conduction. Most MS patients I have talked to who are taking the drug under prescription are informed as to the potential dangers of overdosing and realize the patient weight-dosage relationship of the drug. As with any drug, there is potential for misuse. This misuse is only prevented by an informed patient with a open discussion between their pharmacist, physician and themselves. My wife who is a veteran of the current therapies for MS including solu-medrol IV, Betaseron, Avonex, Copaxone and a clinical trail participant for Linomide is acutely aware of the potential benefits and side effects of drug therapies for MS. I feel that her experience with trials of drugs is not uncommon in the MS patient community and has created a hardy patient group who are proactive in understanding and meeting the challenge of the disease and symptomology. With MS, many patients I feel are not expecting a cure, but are attempting to improve the quality of their life by taking the available prescribed immuno-modulator drugs with no guarantee of efficacy. I believe by my own observations and discussions with MS patients, discussions with neurologists and by studying the available research information, 4 Aminopyridine does provide a benefit in modest improvement of neurological function.. It is understood that 4AP has a short life in the body and dosage is required at timed intervals during the day. It is typical for a patient to spend approximately $50.00 a month for low dosage of 15 mg a day.

My wife and I are involved with the local branch of the National Multiple Sclerosis Society and their support groups. A number of MS patients attending these groups who are taking prescribed 4AP, have expressed disappointment in the event the availability of the drug would be altered.

In closing, I hope I have given the committee information of value in making a decision to include 4 Aminopyridine on the Bulk Drug List and to provide for continue availability to those MS patients and their physicians for which it provides neurological benefit.

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